Pairing ISO standard series with new IEST Recommended Practices

Keeping up with new challenges in contamination control across industries requires understanding of the synergies between ISO standards and IEST RPs

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Following the article titled "New Challenges in Contamination Control" published in the January issue of CleanRooms *magazine, IEST has received positive comments and additional requests for insight into relevant ISO standards applicable to contamination control in controlled environments.*

This article is intended to respond to contamination control communities and aims to de-codify the relevance and myths between IEST RPs and ISO standards, all of which are published by the Institute of Environmental Sciences and Technology (IEST).

As an ANSI-accredited, leading standards writing organization in contamination control, IEST consists of the Contamination Control and the Design, Test, and Evaluation/Product Reliability Divisions, along with the headquarters staff who handle technical committee meetings, standards publishing, information dissemination, and education programs that have served these industries since 1953.

A number of Recommended Practices (RPs) and Reference Documents (RDs) have been developed and published to meet the needs in contamination control and help the industries to advance practices. These valuable documents resulted from collective voluntary efforts and contributions by numerous scientists, engineers, and contamination control professionals from all over the world who have interacted closely in working group meetings, seminars, and sometimes tutorials. While many of the experts focused on RP or RD development, many others were also involved in ISO standards development to collectively address issues regarding contamination control in controlled environments.

As mentioned previously, many IEST RPs and RDs are primary references and sources of information for compliance with the ISO 14644 series of International Standards developed by ISO Technical Committee (ISO/TC) 209, *Cleanrooms and associated controlled environments*. In addition, IEST is a voting member of the ANSI-accredited U.S. Technical Advisory Group (TAG) to ISO/TC 229, *Nanotechnologies*. Not meant to be an exhaustive list, the following table lists the relevance of IEST RPs/RDs and the ISO standards applicable to contamination control in controlled environments. In many cases, the ISO standards focus on "what" issues to address, while RPs focus more on techniques and approaches of "how" to tackle problems relevant to issues addressed by ISO standards.

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ISO Standard	IEST Standard and Practice Committee Documents—Recommended Practice or Reference Document
ISO 14644-1 Classification of Air Cleanliness (1999)	CC001.4: HEPA and ULPA Filters (2005) CC006.3: Testing Cleanrooms (2004) CC012.2: Considerations for Cleanroom Design (revision in progress) CC019: Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices CC036.1: Testing Fan Filter Unit (to be published)
ISO 14644-2 Specifications for Testing and Monitoring to Prove Continued Compliance with 14644-1 (2000)	CC001.4: HEPA and ULPA Filters (2005) CC002.2: Unidirectional Flow Clean-Air Devices (2004) CC006.3: Testing Cleanrooms (2004) CC007.2: Testing ULPA Filters (revision in progress) CC012.2: Considerations for Cleanroom Design (revision in progress) CC034.2: HEPA and ULPA Filter Leak Tests (2005) CC036.1: Testing Fan Filter Unit (to be published)
ISO 14644-3 Test Methods (2005)	CC006.3: Testing Cleanrooms (2004) CC007.2: Testing ULPA Filters (revision in progress) CC008.2: High-efficiency Gas-phase Adsorber Cells (revision in progress) CC013.2: Calibration Procedures and Guidelines for Selecting Equipment Used in Testing Cleanrooms and Other Controlled Environments (2006) CC014.1: Calibration and Characterization of Optical Airborne Particle Counters (2006) CC021.2: Testing HEPA and ULPA Filter Media (2005) CC034.2: HEPA and ULPA Filter Leak Tests (2005) CC036.1: Testing Fan Filter Unit (to be published)
ISO 14644-4 Design, Construction and Start-Up (2001)	CC006.3: Testing Cleanrooms (2004) CC007.2: Testing ULPA Filters (revision in progress) CC008.2: High-efficiency Gas-phase Adsorber Cells (revision in progress) CC012.2: Considerations in Cleanroom Design (revision in progress) CC018.4: Cleanroom Housekeeping–Operating and Monitoring Procedures (revision in progress) CC021.2: Testing HEPA and ULPA Filter Media (2005) CC022.2: Electrostatic Charge in Cleanrooms and Other Controlled Environments (2004) CC024.1: Measuring and Reporting Vibration in Microelectronics Facilities (1994) CC036.1: Testing Fan Filter Unit (to be published)
ISO 14644-5 Operations (2004)	CC003.3: Garment System Considerations in Cleanrooms and Other Controlled Environments (2003) CC004.3: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments (2004) CC008.2: High-efficiency Gas-phase Adsorber Cells (revision in progress) CC005.3: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments (2003) CC018.4: Cleanroom Housekeeping–Operating and Monitoring Procedures (revision in progress)

continued on page 22

continued from page 21

	CC019.1: Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices (2006)
	CC020.2: Substrates and Forms for Documentation in Cleanrooms (1996)
	CC022.2: Electrostatic Charge in Cleanrooms and Other Controlled Environments (2004)
	CC026.2: Cleanroom Operations (2004)
	CC027.2: Personnel Practices and Procedures in Cleanrooms and Controlled Environments (2006)
ISO/DIS 14644-6 Vocabulary (2005)	CC001: HEPA and ULPA Filters
	CC002: Unidirectional Flow Clean-Air Devices
	CC003: Garment System Considerations for Cleanrooms and Other Controlled Environments
	CC004: Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
	CC005: Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
	CC006: Testing Cleanrooms
	CC007: Testing ULPA Filters
	CC008: Gas-Phase Adsorber Cells
	CC009: Compendium of Standards, Practices, Methods, and Similar Documents Relating to Contamination Control
	CC011: A Glossary of Terms and Definitions Relating to Contamination Control
	CC012: Considerations in Cleanroom Design
	CC013: Calibration Procedures and Guidelines for Select Equipment used in Testing Cleanrooms and Other Controlled Environments
	CC014: Calibrating Particle Counters
	CC016: The Rate of Deposition of Nonvolatile Residue in Cleanrooms
	CC018: Cleanroom Housekeeping–Operating and Monitoring Procedures
	CC019: Qualifications for Organizations Engaged in the Testing and Certification of Cleanrooms and Clean-Air Devices
	CC020: Substrates and Forms for Documentation in Cleanrooms
	CC021: Testing HEPA and ULPA Filter Media
	CC022: Electrostatic Charge in Cleanrooms and Other Controlled Environments
	CC023: Microorganisms in Cleanrooms
	CC024: Measuring and Reporting Vibration in Microelectronics Facilities
	CC025: Evaluation of Swabs Used in Cleanrooms
	CC026: Cleanroom Operations
	CC027: Personnel in Cleanrooms
	CC028: Minienvironments
	CC031: Outgassing Performance Criteria for Cleanroom Materials
	CC032: Flexible Packaging Materials for use in Cleanrooms and Other Controlled Environments
	CC034: HEPA and ULPA Filter Leak Tests
	CC035: Design Considerations for Airborne Molecular Contamination Filtration Systems in Cleanrooms
	CC036: Testing Fan Filter Units

continued on page 24

continued from page 22

	CC040: Cleaning of Equipment Surfaces in the Cleanroom and Controlled Environments CC041: Recovery Plan Following Disaster Disruption CC042: Liquid Particle Counters CC101: Forum on Air Cleanliness Technology CC201: Forum for Nanoscale Research Facilities CC901: IEST-STD-CC1246D: Product Cleanliness Levels and Contamination Control Program CC902: MIL-HDBK-406: Contamination Control Technology: Cleaning Materials for Precision Pre-Cleaning and Use in Cleanrooms and Clean Work Stations; MIL-HDBK-407: Contamination Control Technology: Precision Cleaning Methods and Procedures
ISO 14644-7 Separative Devices (2004)	CC002.2: Unidirectional Flow Clean-air Devices (2004) CC008.2: High-efficiency Gas-phase Adsorber Cells (revision in progress) CC012.2: Considerations in Cleanroom Design (revision in progress) CC028.1: Minienvironments (2002) CC036.1: Testing Fan Filter Unit (to be published)
ISO 14644-8 Classification of Airborne Molecular Contamination (2006)	CC016.2: The Rate of Deposition of Nonvolatile Residue in Cleanrooms (2002) CC031.1: Method of Characterizing Outgassed Organic Compounds from Cleanroom Materials and Components (2003)
ISO 14644-9 Clean Surfaces (pending)	TBD
ISO 14698-1 Biocontamination Control–General Principles (2003)	CC013.2: Calibration Procedures and Guidelines for Selecting Equipment Used in Testing Cleanrooms and Other Controlled Environments (2006) CC023.2: Microorganisms in Cleanrooms (2006)
ISO 14698-2 Biocontamination Control–Evaluation and Interpretation of Biocontamination Data (2003)	CC013.2: Calibration Procedures and Guidelines for Selecting Equipment Used in Testing Cleanrooms and Other Controlled Environments (2006) CC023.2: Microorganisms in Cleanrooms (2006)
ISO/DTR 14698-3 Biocontamination Control–Methodology for Measuring the Efficiency of Processes of Cleaning and/or Disinfection of Inert Surfaces Bearing Biocontaminated Wet Soiling or Biofilms (1998)	CC013.2: Calibration Procedures and Guidelines for Selecting Equipment Used in Testing Cleanrooms and Other Controlled Environments (2006) CC023.2: Microorganisms in Cleanrooms (2006)
ISO 21501-4 Determination of particle size distribution–Single particle light interaction methods—Part 4: Light scattering airborne particle counter for clean spaces (2007)	CC014.1: Calibration and Characterization of Optical Airborne Particle Counters (2006)

Documents in the ISO series are in various stages of development, such as the Standard, Final Draft International Standard (FDIS), or Draft International Standard (DIS) stage. In addition, documents may be published as ISO Technical Reports (TR) or ISO Draft Technical Reports (DTR).

As we continue to share with the industries the knowledge and experience gained from our own work, we are continually embracing new challenges and taking advantage of new opportunities to lead the way in the development of ground-breaking documents. We invite you to join in and participate in relevant Working Groups, whether you are from the industrial sector or from academia. For further information, please visit www.iest.org.

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awards for scientific papers, publications, and professional services. At Berkeley Lab, he is involved in the development of innovative methods and protocols that are instrumental in formulating standards to characterize fan filter units. Xu's interests and accomplishments include the production and dissemination of new knowledge and techniques to improve environmental and energy performance of mission-critical buildings, including cleanrooms and minienvironments. He is a technical editor for the *Journal of the IEST* and serves on the editorial board of *Building and Environment*, Elsevier Scientific. He can be contacted at TTXU@LBL.Gov; http://eetd.lbl.gov/Staff/XuTT/.

Anne Marie Dixon is the president of Cleanroom Management Associates, Inc., a consulting firm that specializes in competitive benchmarking, training, and auditing of clean and aseptic operations and management. Dixon has been actively engaged in the field of contamination control for more than 25 years with extensive experience in the areas of training, technical writing, strategic consulting, facility startup, construction protocols, and process optimization. She is a past president of IEST and was awarded the grade of Fellow by IEST in 1998. She chairs the United States Technical Advisory Group to ISO/TC 209 and is head of the U.S. Delegation for ISO/TC 209. Widely published, with more than 100 technical articles and four books, she offers technical courses for IEST, PDA, CCE, IIR, IDEMA, and other associations.

Jan Eudy is the corporate quality assurance manager for Cintas Corporation. At Cintas, Eudy oversees research and development, directs the quality system and ISO registration at all cleanroom locations, and supports validation and sterile services. She established and implemented the HACCP program at Cintas. She is a past president of IEST and an active member of other professional organizations, including the American Society of Clinical Pathologists, the National Registry of Microbiology, the American Society for Microbiology, the American Society for Quality, the International Society for Pharmaceutical Engineers, and the Parenteral Drug Association. Eudy represents Cintas on the FPA Advisory sub-committee to the FDA for the revision of the Food Processing cGMPs. Eudy graduated with a degree in medical technology from the University of Wisconsin with graduate studies in medical microbiology at Creighton University. Her additional qualifications include registered medical technologist and specialist in microbiology with ASCP, registered microbiologist with NRM in consumer product testing and quality assurance, ISO 9000 lead assessor, and certified quality auditor with ASQ.

About IEST

Founded in 1953, IEST is an international technical society of engineers, scientists and educators that serves its members and the industries they represent (simulating, testing, controlling and teaching the environments of earth and space) through education and the development of recommended practices and standards. IEST is an ANSI-accredited standards-developing organization; Secretariat of ISO/TC 209 Cleanrooms and associated controlled environments; Administrator of the ANSI-accredited US TAGs to ISO/TC 209 and ISO/TC 142 Cleaning equipment for air and other gases; and a founding member of the ANSI-accredited US TAG to ISO/TC 229 Nanotechnologies.